

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
8 January 2004 (08.01.2004)

PCT

(10) International Publication Number
WO 2004/003155 A3

- (51) International Patent Classification⁷: **C07H 21/04**,
C07K 16/00, A61K 39/395, G01N 33/53
- (21) International Application Number:
PCT/US2003/020367
- (22) International Filing Date: 26 June 2003 (26.06.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/393,077 28 June 2002 (28.06.2002) US
- (71) Applicant (for all designated States except US): **THE GOVERNMENT OF THE UNITED STATES OF AMERICA**, as represented by **THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES** [US/US]; c/o National Institutes of Health, Office of Technology Transfer, Suite 325, 6011 Executive Boulevard, Rockville, MD 20852-3804 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **KASHMIRI, Syed, V., S.** [US/US]; 11541 Brandy Hall Lane, Gaithersburg, MD 20878 (US). **SCHLOM, Jeffrey** [US/US]; 10301 Sorrel Avenue, Potomac, MD 20854 (US). **PADLAN, Eduardo, A.** [US/US]; 4006 Simms Drive, Kensington, MD 20895 (US).
- (74) Agent: **SIEGEL, Susan, Alpert**; Klarquist, Sparkman, LLP, One World Trade Center, Suite 1600, 121 SW Salmon Street, Portland, OR 97204 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Declaration under Rule 4.17:**
— of inventorship (Rule 4.17(iv)) for US only
- Published:**
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report:
17 June 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HUMANIZED ANTI-TAG-72 CC49 FOR DIAGNOSIS AND THERAPY OF HUMAN TUMORS

(57) Abstract: The present disclosure provides humanized CC49 monoclonal antibodies that bind TAG-72 with high binding affinity and that are minimally immunogenic. In one embodiment, a humanized CC49 antibody includes a non-conservative amino acid substitution in a light chain complementarity determining region 3 of the CC49 antibody. In a further embodiment, the humanized CC49 antibody includes a non-conservative substitution of a first residue in a light chain complementarity determining region 3 and a substitution of a second residue in a complementarity determining region of the humanized CC49 antibody. In several of the embodiments, methods are disclosed for the use of a humanized CC49 antibody in the detection or treatment of a tumor in a subject. Also disclosed is a kit including the humanized CC49 antibody described herein.

WO 2004/003155 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/20367

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07H 21/04; C07K 16/00; A61K 39/395; G01N 33/53

US CL : 536/23.53; 435/320.1, 7.1; 530/387.1, 388.85, 391.1; 424/133.1, 156.1, 181.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536/23.53; 435/320.1, 7.1; 530/387.1, 388.85, 391.1; 424/133.1, 156.1, 181.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/26394 (THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES) 11 May 2000 (11/05/00), see entire document, especially Figure 2, page 25, lines 1-11, page 14, line 15-22, page 14-19.	1, 4-19, 21-22, 32-50,
---		52
Y		----- 51, 53-54

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

26 November 2003 (26.11.2003)

Date of mailing of the international search report

04 MAY 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Authorized officer

Larry R. Helms

Telephone No. 571/272 -1600

INTERNATIONAL SEARCH REPORT

PCT/US03/20367

Continuation of B. FIELDS SEARCHED Item 3:

CAPLUS MEDLINE BIOSIS WEST

Search terms: CC49, antibody, CDR grafted, humanized, human, LEN, TAG-72, inventor name